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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,140	01/19/2001	Donald Michael Black	5950-01-CA	3004

7590

08/09/2005

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,140

Applicant(s)

BLACK, DONALD MICHAEL

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6 and 11-13 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1,5,6 and 11-13 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6-20-05 have been fully considered but they are not persuasive.
2. Regarding the 35 USC 112, first paragraph rejection Applicant contends support is provided at Example 1 on page 7 and page 25 lines 5-24. The Examiner disagrees because the specification does not support the transitional phrase "consisting of". Example 1 of Applicant's specification describes a medical method including administering Atorvastatin in combination with a requirement for reduced alcohol consumption (page 10, line 12), occasional use of antacids (page 11, line 25), the suggestion to take one aspirin daily (page 16, line 4), and suggestion to modify diet, smoking, and exercise habits (page 17 lines 15-17). The transitional phrase "consisting of" defines the method to include only the recited steps. The specification must provide support for such method. MPEP 2163 II A-1 recites, "The claim as a whole, including all limitations found in the preamble, transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement. An applicant show possession of the claimed invention by describing the claimed invention with all its limitations." The Examiner has found no written support in the specification for a method comprising the sole step of administering Atorvastatin.
3. Arguments pertaining to Seed and Bocan are now moot in view of the new grounds of rejection set forth below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
2. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
3. Claims 1,5,6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the limitation "consisting of" lacks sufficient support in the originally filed specification. Applicant describes at page 10, line 12 the requirement for limited alcohol consumption, page 16 line 4 suggests administration of aspirin, and page 17 line 17 describes modifications to diet, smoking, and exercises. Therefore modifications to diet, supplemental drugs, and reducing alcohol intake are included in applicant's disclosed method. Applicant's disclosure fails to disclose a method comprising solely the step of administering cholesterol-lowering

agents. For purposes of examination "consisting of" is interpreted to distinguish the number of drugs used but the overall method may include dietary modifications.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1,5,6,11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bocan WO 97/16184.

6. Bocan discloses in lines 16-24 and 28-36 of page 2, 12-35 of page 3, 1-12 of col. 5, and 7-22 a method of administering 80mg/day of Atorvastatin alone in patients having coronary artery disease in need of revascularization treatment resulting in an aggressive lowering of LDL cholesterol by about 50%. Note Bocan discloses both administration of Atorvastatin or Atorvastatin in combination with other drugs.

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

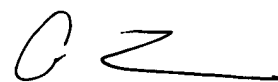
Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



WHM
August 8, 2005



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